IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF GEORGIA
ROME DIVISION

CHARLES HENDERSON	:	Index No.:
Plaintiff,	:	
v.	:	**COMPLAINT** **JURY TRIAL DEMANDED**
SUN PHARMACEUTICALS INDUSTRIES, LTD; SUN PHARMA GLOBAL, INC.; CARACO PHARMACEUTICAL LABORATORIES, LTD; HOSPIRA, INC., HOSPIRA WORLDWIDE, INC.; UDL LABORATORIES, INC.; MYLAN, INC. F/K/A MYLAN LABORATORIES, INC.; MYLAN BERTEK PHARMACEUTICALS, INC.; and MYLAN PHARMACEUTICALS, INC.,	:	
Defendants.	:	

COMES NOW, Charles Henderson, complaining of the above-listed Defendants, and for causes of action would respectfully show this Honorable Court as follows:

PARTIES

1. Plaintiff, CHARLES HENDERSON, is a citizen and resident of Rome, Georgia.

2. Sun Pharmaceutical Industries, Ltd., is a foreign corporation organized under the laws of India and located at Acme Plaza, Andheri-Kurla Rd, Andheri (E) Mumbai, 400059, Republic of India.

3. Sun Pharmaceutical Industries, Ltd, all times relevant herein was in the business of designing, testing, manufacturing, labeling, advertising, marketing, promoting, selling and

distributing Phenytoin drug products in the stream of commerce for use by the public, including plaintiff.

4. Defendant Sun Pharmaceutical Industries, Ltd, at all time's material hereto has and continues to do business in this state.

5. Defendant Caraco Pharmaceutical Laboratories, Ltd. ("Caraco") is a Michigan corporation with its principal place of business in Detroit, Michigan and is controlled by Sun.

6. Upon information and belief, as of March 31, 2009, Sun's beneficial ownership of Caraco stock is 74% (76% including its convertible Series B Preferred Stock). Upon information and belief Caraco develops, manufacturers, markets and distributes generic pharmaceuticals to wholesalers, distributors, drugstore chains and managed-care providers on behalf of SUN Pharmaceuticals Industries LTD, and SUN Pharma Global, Inc.

7. Sun Pharma Global, Inc., a wholly owed subsidiary of Sun Pharmaceuticals Industries, Ltd., is located in the British Virgin Islands, and maintains a post office box at International Trust Building, P.O. Box 659, Road Town, Tortola, British Virgin Islands.

8. Sun Pharma Global, Inc., all times relevant herein was in the business of designing, testing, manufacturing, labeling, advertising, marketing, promoting, selling and distributing Phenytoin drug products in the stream of commerce for use by the public, including plaintiff.

9. Defendant Sun Pharma Global, Inc., at all time's material hereto has and continues to do business in this state.

10. At all times hereafter defendants' SUN PHARMACEUTICALS, INDUSTRIES LTD; SUN PHARMA GLOBAL, INC., and CARACO PHARMACEUTICAL LABORATORIES, LTD, will be known as "SUN".

11. Defendant HOSPIRA, INC., (hereinafter "Hospira" and/or pharmaceutical defendant) is a corporation incorporated under the laws of the state of *Delaware* with its principal place of business in Illinois. Defendant Hospira may be served with process through its registered agent, CT Corporation, located at 1201 Peachtree Street, NE, Atlanta, GA 30361.

12. At all times relevant hereto, Defendant Hospira was and continues to be engaged in the business of testing, developing, manufacturing, distributing, licensing, labeling and marketing, either directly or indirectly through third parties or related entities, the pharmaceutical drug, Phenytoin.

13. Defendant HOSPIRA WORLDWIDE, INC., (hereinafter "Hospira Worldwide" and/or pharmaceutical defendant) is a corporation incorporated under the laws of the state of *Delaware* with its principal place of business in Illinois. Defendant Hospira may be served with process through its registered agent, CT Corporation, located at 1201 Peachtree Street, NE, Atlanta, GA 30361.

14. At all times relevant hereto, Defendant Hospira was and continues to be engaged in the business of testing, developing, manufacturing, distributing, licensing, labeling and marketing, either directly or indirectly through third parties or related entities, the pharmaceutical drug, Phenytoin.

15. *At all times hereafter defendants HOSPIRA, INC. and HOSPIRA WORLDWIDE, INC. will be known as "Hospira".*

16. Defendant UDL Laboratories, Inc., is a foreign corporation, with its headquarters and principal place of business at 1718 Northrock Court, Rockford, IL, 61103.

17. The agent for service of process for Defendant UDL Laboratories, Inc. is located at 801 Adlai Stevenson Drive, Springfield, IL 62703.

18. Defendant Mylan, Inc. f/k/a Mylan Laboratories, Inc. ("Mylan Laboratories") is a Pennsylvania corporation with its principal place of business located at 1500 Corporate Drive, Suite 400, Cannonsburg, Pennsylvania 15317. Although Mylan, Inc. has failed to register with the Georgia Secretary of State, Mylan Laboratories, Inc. was previously registered with the Georgia Secretary of State. The last identified registered agent for Mylan Laboratories, Inc. in Georgia is CT Corporation System, located at 1201 Peachtree Street, NE, Atlanta, Georgia 30361. Defendant Mylan Laboratories is subject to the jurisdiction and venue of this Court. At all times herein mentioned, Defendants were engaged in the business of manufacturing, packaging, marketing, distribution, promotion, and sale of extended phenytoin sodium capsules, and at all times herein relevant were engaged in the promotion and marketing of pharmaceutical products, including extended phenytoin sodium capsules, in the State of Georgia.

19. Defendant Mylan, Inc. f/k/a Mylan Laboratories, Inc. ("Mylan Laboratories") is a Pennsylvania corporation with its principal place of business located at 1500 Corporate Drive, Suite 400, Cannonsburg, Pennsylvania 15317. Although Mylan, Inc. has failed to register with the Georgia Secretary of State, Mylan Laboratories, Inc. was previously registered with the Georgia Secretary of State. The last identified registered agent for Mylan Laboratories, Inc. in Georgia is CT Corporation System, located at 1201 Peachtree Street, NE, Atlanta, Georgia 30361. Defendant Mylan Laboratories is subject to the jurisdiction and venue of this Court. At all times herein mentioned, Defendants were engaged in the business of manufacturing, packaging, marketing, distribution, promotion, and sale of extended phenytoin sodium capsules, and at all times herein relevant were engaged in the promotion and marketing of pharmaceutical products, including extended phenytoin sodium capsules, in the State of Georgia.

20. Defendant Mylan Pharmaceuticals, Inc. ("Mylan Pharmaceuticals") is a West Virginia corporation with its principal place of business located in West Virginia. Defendant Mylan Pharmaceuticals is subject to the jurisdiction and venue of this Court. At all times herein mentioned, Defendants were engaged in the business of manufacturing, packaging, marketing, distribution, promotion, and sale of extended phenytoin sodium capsules, and at all times herein relevant were engaged in the promotion and marketing of pharmaceutical products, including extended phenytoin sodium capsules, in the State of Georgia.

21. Defendant Mylan Pharmaceuticals, Inc. can be served by service on its registered agent: Corporation Service Company, 40 Technology Parkway South, #300, Norcross, Georgia 30092.

22. Defendant Mylan Bertek Pharmaceuticals, Inc. ("Mylan Bertek") is a Texas corporation. Defendant Mylan Bertek is subject to the jurisdiction and venue of this Court. At all times herein mentioned, Defendants were engaged in the business of manufacturing, packaging, marketing, distribution, promotion, and sale of extended phenytoin sodium capsules, and at all times herein relevant were engaged in the promotion and marketing of pharmaceutical products, including extended phenytoin sodium capsules, in the State of Georgia.

23. Defendant Mylan Bertek Pharmaceuticals, Inc. is not properly registered with the Georgia Secretary of State, but may be served with process through its Texas registered agent: Corporation Service Company, d/b/a CSC-Lawyers INCO, 701 Brazos Street, Suite 1050, Austin, Texas 78701.

24. Hereafter defendants' Mylan, Inc. f/k/a Mylan Laboratories, Inc., Mylan Bertek Pharmaceuticals, Inc., and Mylan Pharmaceuticals, Inc. shall be known as "Mylan".

JURISDICTION AND VENUE

25. Jurisdiction exists as against the defendants, pursuant to 28 U.S.C. Section 1332, in that the Plaintiff, is a citizen and resident of the State of Georgia, and the defendants are foreign corporations; thus, complete diversity exists between the parties; the amount in controversy exceeds the sum of $75,000.00; venue is proper under 28 U.S.C. Section 1391(2) as plaintiff ingested the drug in this district and was subsequently injured in this district; thus, a substantial part of the events or omissions giving rise to plaintiff's claim occurred in this district

GENERAL ALLEGATIONS

26. On or about February 16, 2009, Charlie Henderson was admitted to Floyd Medical Center for treatment of brain lesions and was prescribed and administered fosphenytoin and phenytoin for treatment of seizure disorder.

27. On or about February 18, 2009, Charlie Henderson was administered Defendant Hospira's fosphenytoin IV, NDC 00409-4857-10 at Floyd Medical Center, 304 Turner McCall Blvd, Rome, Georgia.

28. On or about February 18, 2009, Charlie Henderson filled a prescription of phenytoin with Defendant Mylan's product at Walgreens, 213 Turner McCall Blvd., Rome, Georgia 30165.

29. On or about February 19, 2009, Charlie Henderson filled a prescription of phenytoin at Walgreens pharmacy, 213 Turner McCall Blvd, Rome, Georgia 30165, with Defendant UDL's product, NDC #51079-0905-20. Mr. Henderson ingested UDL's product pursuant to physician orders until on or about March 10, 2009.

30. On or about March 10, 2009, Charlie Henderson filled a prescription of phenytoin with Defendant Sun's product at CVS Pharmacy, 1103 Calhoun Avenue, Rome, Georgia, 30167.

Mr. Henderson ingested Defendant's Sun's product, NDC #62756-0402-03, pursuant to physician orders.

31. Following his use of the above seizure medication, fosphenytoin and phenytoin, Mr. Henderson suffered a severe adverse reaction which upon information and belief constitutes one or more of the following, sometimes overlapping, severe skin conditions: erythema multiforme exudativum, bullous fixed drug eruption, severe cutaneous adverse reaction, acute generalized exanthematous pustulosis, drug reaction with eosinophilia and systemic symptoms, Toxic Epidermal Necrolysis and Stevens-Johnson Syndrome.

32. After developing said condition, the Plaintiff, CHARLES HENDERSON, discovered that said injuries were or may have been caused by the negligent acts or omissions of the Defendants.

33. As more particularly pled below, aforementioned Plaintiff, CHARLES HENDERSON maintains that said drug is defectively designed, inadequately tested, dangerous to human health, and lacked proper warnings as to the dangers associated with its use.

34. Phenytoin is the generic name of Dilantin, an anticonvulsant agent indicated to prevent seizures. Defendants manufactured, designed, packaged, marketed, sold and distributed this drug.

35. Fosphenytoin is a prodrug and is converted in the body to phenytoin.

33. Phenytoin belongs to the therapeutic class of drugs known as anticonvulsants and is approved by the U.S. Food and Drug Administration to control generalized tonic-clonic (grand mal) and complex partial seizures and prevention and treatment of seizures occurring during or following neurosurgery. Defendants each manufactured, designed, packaged, marketed, sold and distributed this drug.

34. Defendants' phenytoin products carry the highest risk, of Stevens Johnson Syndrome and Toxic Epidermal Necrolysis (SJS/TEN), which are associated with these cutaneous syndromes, of all anti-convulsant drugs on the market.

35. Post-marketing databases confirm that serious skin reactions have been reported in patients receiving phenytoin drug products. These databases include the US-FDA Adverse Event Reporting System (AERS), World Health Organization (WHO), Upsalla Monitoring Centre, and the Health Canada Adverse Event Database and demonstrated that SJS/TEN events associated with phenytoin drug products were not infrequent and exceeded other drugs on the market that have significant relative risks of SJS/TEN, including Bactrim and Tegretol.

36. Defendants failed to analyze the data from WHO, and in doing so, failed to prevent the excessive number of fatalities and disabling injuries occurring in survivors of SJS/TEN caused by its phenytoin drug products over the last three decades.

37. The total number of SJS/TEN cases reported to the WHO database is 1,172 reports of SJS/TEN between 1969-2006, with 831 reports of SJS and 341 reports of TEN, with a mortality rate that ranges between 30-80%.

38. The total number of reports of SJS/TEN for phenytoin drug products reported in the FDA AERS database is 1,062.

39. Per the FDA AERS database, phenytoin drug products are the primary responsible drugs accounting for 139 deaths of 718 SJS/TEN reports where phenytoin was the primary reported agent and another 188 deaths of 879 reports where phenytoin was the secondary or concomitant drug reported.

40. Defendants' phenytoin drug products are the most dangerous and lethal drugs that cause deaths from SJS/TEN.

41. Phenytoin drug products have nearly a 6 times greater reporting ratio of SJS/TEN than Bextra and Trileptal, yet Defendants' Phenytoin drug products have no Black Box Warnings or any specific warnings for these side effects, even though its risk of SJS/TEN far exceed other drugs.

42. Defendants' failed to analyze the data from WHO, and in doing so, failed to prevent the excessive number of fatalities and disabling injuries occurring in survivors of SJS/TEN caused by its Phenytoin drug products over the last three decades.

43. The total number of SJS/TEN cases reported to the WHO database is 1,172 reports of SJS/TEN between 1969-2006, with 831 reports of SJS and 341 reports of TEN, with a mortality rate that ranges between 30-80%.

44. The total number of reports of SJS/TEN for Phenytoin drug products reported in the FDA AERS database is 1,062.

45. Per the FDA AERS database, Phenytoin drug products are the primary responsible drugs accounting for 139 deaths of 718 SJS/TEN reports where Phenytoin was the primary reported agent and another 188 deaths of 879 reports where Phenytoin was the secondary or concomitant drug reported.

46. The data above was available to Defendants' before and after they marketed phenytoin to the public.

47. The labeling for Defendants' phenytoin drug products reports that the risk of SJS/TEN and renal failure is rare, this is inaccurate, misleading and false.

48. Defendants' never provided sufficient information regarding the risk of SJS/TEN to prescribing physicians or patients, including the decedent.

49. Defendants' never disseminated to patients or the medical community appropriate instructions or measures that a patient should undertake if the early symptoms of SJS/TEN develop

while using its phenytoin products in order to reduce the risk of occurrence of these serious conditions cutaenous reactions and renal failure.

50. Defendants' have had ample opportunity to change their labeling to provide adequate warnings and sufficient warnings on the safe use of phenytoin drug products to reduce or avoid the risk of SJS/TEN and renal failure, but failed to act.

51. Defendants' have failed to add adequate information or warning regarding the predisposition of African Americans and/or Asians to SJS/TEN and renal failure from the use of its drug.

52. Defendants' misrepresented and failed to appropriately warn the medical community and patients, including Plaintiff, that use of phenytoin may increase the risk of Stevens Johnson Syndrome and/or Toxic Epidermal Necrolysis, organ failure, and/or death, thereby placing its profits above the safety of the public.

53. Plaintiff has endured and continues to suffer from mental anguish from the knowledge that these injuries were a result of Defendants' wrongful acts and omissions.

54. As a result of claims made by Defendants regarding the safety and effectiveness of Defendants' Phenytoin product, Mr. Henderson suffered severe, painful and permanent injuries, specifically a severe adverse reaction of erythema multiforme exudativum, bullous fixed drug eruption, severe cutaneous adverse reaction, acute generalized exanthematous pustulosis, drug reaction with eosinophilia and systemic symptoms, Stevens Johnson Syndrome or Toxic Epidermal Necrolysis.

55. These conditions and the resulting injuries were caused by Mr. Henderson's ingestion of Defendants' Phenytoin product,.

56. Had Mr. Henderson known the risks and dangers associated with Defendants' Phenytoin product, or had Defendants' disclosed such information to Mr. Henderson or his prescribing physicians, he would not have taken Defendants' Phenytoin product and would not have suffered his adverse reaction and its subsequent complications.

57. Upon information and belief, as a result of the manufacturing and marketing Defendants' Phenytoin product, Defendants have reaped huge profits; while concealing from the public, knowledge of the potential hazard associated with the ingestion of Defendants' Phenytoin product.

58. Defendants failed to perform adequate testing in that the adequate testing would have shown that Defendants' Phenytoin product possessed serious side effects with respect to which Defendants should have taken appropriate measures to ensure that its defectively designed product would not be placed into the stream of commerce and/or should have provided full and proper warnings accurately and fully reflecting the scope and severity of symptoms of those side effects should have been made.

59. Prior to the manufacturing, sale, and distribution of Defendants' Phenytoin product, Defendants', through their officers, directors and managing agents, had notice and knowledge from several sources, prior to the date of the marketing and sale of Defendants' Phenytoin product to Mr. Henderson, that the products presented substantial and unreasonable risks of harm to the consumer. As such, said consumers, including Mr. Henderson, were unreasonably subjected to risk of injury or death from the consumption of Defendants' Phenytoin product.

60. Despite such knowledge, Defendant, through its officers, directors and managing agents for the purpose of increasing sales and enhancing its profits, knowingly and deliberately failed to remedy the known defects of Defendants' Phenytoin product and failed to adequately warn

the public, including Mr. Henderson, of the serious risk of injury occasioned by the defects inherent in Defendants' Phenytoin product. Defendants' and their officers, agents and managers intentionally proceeded with the manufacturing, sale and marketing of Defendants' Phenytoin product, knowing that persons would be exposed to serious potential danger, in order to advance their own pecuniary interests. Defendants conduct was wanton and willful, and displayed a conscious disregard for the safety of the public and particularly of Mr. Henderson, entitling his to exemplary damages.

61. Defendants acted with conscious and wanton disregard of the health and safety of Mr. Henderson, who requests an award of additional damages for the sake of example and for the purpose of punishing such entities for its conduct, in an amount sufficiently large to be an example to others, and to deter Defendants and others from engaging in similar conduct in the future. The above-described wrongful conduct was done with knowledge, authorization, and ratification of officers, directors, and managing agents of Defendant.

62. As a result of ingesting the products manufactured, supplied, and/or sold by Defendant, Mr. Henderson suffered severe, painful and permanent injuries, specifically a severe adverse reaction of erythema multiforme exudativum, bullous fixed drug eruption, severe cutaneous adverse reaction, acute generalized exanthematous pustulosis, drug reaction with eosinophilia and systemic symptoms, Stevens Johnson Syndrome or Toxic Epidermal Necrolysis. As a result of the dangerously defective nature of Defendants' Phenytoin product at the time of manufacture and distribution, Mr. Henderson, by using Phenytoin, sustained the injuries and damages as herein alleged. To this day, Mr. Henderson has trouble with scarring do to the effects of erythema multiforme exudativum, bullous fixed drug eruption, severe cutaneous adverse reaction, acute

generalized exanthematous pustulosis, drug reaction with eosinophilia and systemic symptoms, Stevens - Johnson syndrome or Toxic Epidermal Necrolysis.

63. As a direct and proximate result of Defendants' negligence as described herein, Mr. Henderson has sustained harm, including permanent and debilitating injuries. As a result of the acts and omissions of Defendant, Mr. Henderson suffered severe, painful and permanent injuries, specifically an erythema multiforme exudativum, bullous fixed drug eruption, severe cutaneous adverse reaction, acute generalized exanthematous pustulosis, drug reaction with eosinophilia, systemic symptoms of Stevens Johnson Syndrome or Toxic Epidermal Necrolysis and resultant injury, harm and economic loss as set forth herein.

LIABILITY OF GENERIC DRUG MANUFACTURER

64. Phenytoin is a generic for the drug Dilantin (made by Pfizer, previously, Parke Davis – referred to as "Pfizer") and was approved as a bioequivalent by the FDA in December, 1998.

65. When a generic drug manufacturer files its Abbreviated New Drug Application (ANDA) their label need be the "same as" the innovators (Pfizer), 21 CFR 314.94(a)(8)(iv), thereafter it immediately acquires the duty and obligation to search available medical literature, databases and report serious adverse events from any source to the FDA, which could compel or lead to the revision of labeling for their product by the FDA or by Defendants. See 21 CFR 314.80-81 & 314.70(c)(6)(iii).

66. The FDA has clearly anticipated the situation in which generic drug manufacturers gain access to critical safety information and provided procedures for them to independently strengthen their labeling. [See 21 CFR 314.70(c)(2)(ii) & FDA Guidance "Changes to Approved NDA or ANDA" (November 1999) at 24-25 and Revision 1 to this Guidance, issued April 2004 at 24-26 and the Final Rule published at 69 FR 18728.]

67. FDA's guidance (1999 and 2004) specifically state that the following changes may be effected by the generic sponsor:

> November 1999 Guidance for Industry: Changes to an Approved NDA or ANDA
> A changes being effected supplement should be submitted for any labeling change that (1) adds or strengthens a contraindication, warning, precaution, or adverse reaction, (2) adds or strengthens a statement about drug abuse, dependence, psychological effect or overdose, (3) adds or strengthens an instruction about dosage and administration that is intended to increase the safe use of the product, (4) deletes false, misleading or unsupported indications for use or claims for effectiveness, or (5) is specifically requested by FDA. The submission should include 12 copies of final printed labeling. The following list includes some examples of changes that re currently considered by CDER to fall into this reporting category.
> 1. Addition of an adverse event due to information reported to the applicant or Agency.
> 2. Addition of a precaution arising out of a post marketing study.
> 3. Clarification of the administration statement to ensure proper administration of the drug product.
> 4. Labeling change, normally classified as major changes, that the FDA specifically requests be implemented using a changes being effected supplement.
>
> November 2004 Guidance for Industry; Changes to an Approved NDA or ANDA
> Under § 314.70 (c)(6)(iii), a changes-being-effected supplement must be submitted for any labeling change that (1) adds or strengthens a contraindication, warning, precaution , or adverse reaction, (2) adds or strengthens a statement about drug abuse, dependence, psychological effect or overdose, (3) adds or strengthens an instruction about dosage and administration that is intended to increase the safe use of the product, (4) deletes false, misleading or unsupported indications for use or claims for effectiveness, or (5) normally requires a supplemental submission and approval prior to distribution of the drug product that FDA specifically requests be submitted under this provision. A changes-being-effected supplement that provides for a labeling change under § 314.70(c)(6)(iii), must include 12 copies of final printed labeling (§ 314.70(c)(1)). The following list includes some examples of changes currently considered by CDER to fall into this category.
> 1. Addition of an adverse event due to information reported to the applicant or Agency.
> 2. Addition of a precaution arising out of a post marketing study.
> 3. Clarification of the administration statement to ensure proper administration of the drug product.

68. Accordingly, Defendants' had an ongoing duty to conduct post marketing safety surveillance for any reports of serious adverse events associated with Phenytoin and/or Dilantin, including any such report in the medical literature. The following is a non-exhaustive list of what

Defendants' knew or should have known and what should have compelled it to unilaterally change its label and warn physicians about the dangers and lack of efficacy of its drug Phenytoin:

- Phenytoin causes SJS and TEN.
- Phenytoin probably carries the highest risk of TEN.
- The mortality rate associated with SJS and TEN ranges between 30-80%.
- Depakote and Neurontin are safer SJS/TEN alternatives to Phenytoin.
- For 16 years Phenytoin has been reported in medical literature to be the most pharmacogenetically hazardous drug.
- Phenytoin is the most dangerous and lethal drug to cause deaths from SJS/TEN.
- Per the FDA AERS database, Phenytoin is the primary responsible drug for 139 deaths of 718 SJS/TEN reports where Phenytoin was the primary reported agent (plus another 188 deaths of 879 reports where Phenytoin was the secondary or concomitant drug reported).
- 9 of 10 of the worst SJS/TEN offenders have SJS and/or TEN in the warning section of the label. Phenytoin, the most dangerous, has neither.
- In 1995, in the largest epidemiological study on SJS and TEN, an international case-control study to evaluate the relative risks of drugs associated with SJS and TEN, the Severe Cutaneous Adverse Reaction Study Group (SCAR), authors reported that Phenytoin had a relative risk of 53 of SJS and TEN associated with Phenytoin therapy.
- In another study published in 2002, a multi-center review of TEN cases from 15 burn centers across the U.S. reported that over 20% of all TEN patients were caused by Phenytoin from 1995 to 2000.
- The International League Against Epilepsy (ILAE) concluded that not a single Class I randomized control trial (RCT) exists to establish the efficacy of phenytoin for any type of seizure solely excepting adult patients with partial seizures.

CAUSES OF ACTION

COUNT I
STRICT PRODUCT LIABILITY - FAILURE TO WARN

69. Plaintiff incorporates by reference each and every paragraph of this complaint as though set forth in full in this cause of action.

70. Defendants manufactured, marketed, distributed, and supplied Defendants' Phenytoin product. As such, Defendants had a duty to warn the public, including Mr. Henderson

and his prescribing physicians, of the health risks associated with using Defendants' Phenytoin product.

71. Defendants' Phenytoin product was under the exclusive control of Defendants, and was sold without adequate warnings regarding the risk of serious skin reactions, erythema multiforme exudativum, bullous fixed drug eruption, severe cutaneous adverse reaction, acute generalized exanthematous pustulosis, drug reaction with eosinophilia and systemic symptoms exfoliative dermatitis, toxic epidermal necrolysis, Stevens - Johnson syndrome and other risks associated with its use.

72. As a direct and proximate result of the defective condition of Defendants' Phenytoin product, as manufactured and/or supplied by Defendants, and as a direct and proximate result of negligence, gross negligence, willful and wanton misconduct, or other wrongdoing and actions of Defendants described herein, Plaintiff suffered personal injuries, and economic loss as alleged herein.

73. Upon information and belief, Defendants knew of the defective nature of Defendants' Phenytoin product but continued to design, manufacture, market, and sell Defendants' Phenytoin product so as to maximize sales and profits at the expense of the public health and safety, in knowing, conscious, and deliberate disregard of the foreseeable harm caused by Defendants' Phenytoin product and in violation of their duty to provide an accurate, adequate, and complete warning concerning the use of Defendants' Phenytoin product.

74. Defendants failed to warn the public, Mr. Henderson, or his prescribing physicians of the dangerous propensities of Defendants' Phenytoin product, which dangers were known or should have been known to Defendants, as they were scientifically readily available.

75. Defendants knew and intended that Defendants' Phenytoin product would be prescribed by physicians and would be used by persons with a prescription, without any inspection for defects. Defendants also knew that physicians and users such as Mr. Henderson and his prescribing physicians would rely upon the representations made by Defendants on the product labels and in other promotional and sales materials upon which the Mr. Henderson and his prescribing physician did so rely.

76. As a direct and proximate result of the Defendants' sale of the Phenytoin product without adequate warnings regarding the risk of serious skin reactions, erythema multiforme exudativum, bullous fixed drug eruption, severe cutaneous adverse reaction, acute generalized exanthematous pustulosis, drug reaction with eosinophilia and systemic symptoms exfoliative dermatitis, toxic epidermal necrolysis, Stevens-Johnson Syndrome and other risks associated with its use, Plaintiff suffered harm as alleged herein, including ascertainable economic loss, including the purchase price of Defendants' Phenytoin product, out-pocket costs of medical tests and treatment, future medical care and/or services, and other costs incidental to Mr. Henderson's ingestion of harmful and defective products, as well as extreme pain and suffering, loss of enjoyment of life, and other damages.

77. Defendants' conduct in the packaging, warning, marketing, advertising, promotion, distribution, and sale of Defendants' Phenytoin product, was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers such as Mr. Henderson, thereby entitling Plaintiff to punitive damages in an amount to be determined at trial that is appropriate to punish Defendants and deter them from similar conduct in the future.

COUNT II
STRICT PRODUCT LIABILITY – DEFECTIVE IN DESIGN OR MANUFACTURE

78. Plaintiff incorporates by reference each and every paragraph of this complaint as though set forth in full in this cause of action.

79. Defendants were the manufacturers, sellers, distributors, marketers, and/or suppliers of Defendants' Phenytoin product, which was defective and unreasonably dangerous to consumers.

80. Defendants' Phenytoin product was sold, distributed, supplied, manufactured, marketed, and/or promoted by Defendant, and was expected to reach and did reach consumers without substantial change in the condition in which it was manufactured and sold by Defendant.

81. The Phenytoin product manufactured, supplied, and/or sold by Defendants was defective in design or formulation in that when it left the hands of the manufacturers and/or sellers and was unreasonably dangerous in that its foreseeable risks exceeded the benefits associated with its design or formulation, the foreseeable risks exceeded the benefits associated with the designs or formulations of the product.

82. Upon information and belief, Defendants actually knew of the defective nature of Defendants' Phenytoin product but continued to design, manufacture, market, and sell it so as to maximize sales and profits at the expense of the public health and safety, in conscious disregard of the foreseeable harm caused by Defendants' Phenytoin product.

83. There were safer alternative methods and designs for the product.

84. At all times material, Phenytoin was designed, tested, inspected, manufactured, assembled, developed, labeled, sterilized, licensed, marketed, advertised, promoted, sold, packaged, supplied and/or distributed by Defendants in a defective and unreasonably dangerous condition in ways which include, but are not limited to, one or more of the following:

a. When placed in the stream of commerce, the drug contained unreasonably dangerous design defects and was not reasonably safe and fit for its intended or reasonably foreseeable purpose or as intended to be used, thereby subjecting users and/or consumers of the drug, including Mr. Henderson, to risks which exceeded the benefits of the drug;

b. The drug was insufficiently tested;

c. The drug caused harmful side effects that outweighed any potential utility;

d. The drug was not accompanied by adequate labeling, instructions for use and/or earnings to fully apprise the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Mr. Henderson, of the potential risks and serious side effects associated with its use, thereby rendering Defendants liable to Plaintiff.

e. In light of the potential and actual risk of harm associated with the drug's use, a reasonable person who had actual knowledge of this potential and actual risk of harm would have concluded that Phenytoin should not have been marketed in that condition.

85. At all times material, the drug Phenytoin was designed, tested, inspected, manufactured, assembled, developed, labeled, sterilized, licensed, marketed, advertised, promoted, sold, packaged, supplied and/or distributed, it was expected to reach, and did reach, users and/or consumers of the drug across the United Sates, including Mr. Henderson, without substantial change in the defective and unreasonably dangerous condition in which it was sold.

86. At all times, Mr. Henderson used Phenytoin for its intended or reasonably foreseeable purpose. As a direct, legal proximate and producing result of the defective and

unreasonably dangerous condition of Phenytoin, Mr. Henderson sustained harm, including, among other things, acute, and debilitating injuries and death, for which Plaintiff are entitled to damages. These injuries caused extensive pain and suffering, severe emotional distress, substantially reduced Mr. Henderson's ability to enjoy life, and caused Plaintiff to expend substantial sums of money for medical, hospital and related care.

87. As a direct, legal, proximate and producing result of the defective and unreasonably dangerous condition of Phenytoin, Mr. Henderson was injured in health, strength and activity and suffered physical injuries as well as mental anguish and death. All of said injuries caused Mr. Henderson intense anxiety, distress, fear, pain and suffering secondary to physical injury and damages, for which Plaintiff are entitled to damages.

88. As a direct, legal, proximate and producing result of the defective and unreasonably dangerous condition, Mr. Henderson required reasonable and necessary health care treatment and services and incurred expenses for which Plaintiff are entitled to damages.

89. As a direct and proximate result of the design and manufacturing defects of Defendants' Phenytoin product, Mr. Henderson suffered harm as alleged herein, including ascertainable economic loss, including the purchase price of Defendants' Phenytoin product, out-pocket costs of medical tests and treatment, medical care and/or services, and other costs incidental to Mr. Henderson's ingestion of harmful and defective products, as well as extreme pain and suffering, loss of enjoyment of life, and other injuries.

90. Defendants' aforementioned conduct was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers such as Mr. Henderson, including Defendants' knowingly withholding and/or misrepresenting information to the public including Mr. Henderson, which information was material and relevant to the harm in question, punitive damages

in an amount to be determined at trial that are appropriate to punish Defendants and deter them from similar conduct in the future.

COUNT III
FRAUD

91. Plaintiff incorporates by reference each and every paragraph of this complaint as though set forth in full in this cause of action.

92. At all material times, Defendants were engaged in the business of manufacturing, marketing, distributing, promoting, and selling Defendants' Phenytoin product.

93. Defendants made misrepresentations of material facts to, and omitted and/or concealed material facts from, Mr. Henderson and his prescribing physician in the advertising, marketing, distribution and sale of Defendants' Phenytoin product regarding its safety and use.

94. Defendants deliberately and intentionally misrepresented to, and omitted and/or concealed material facts from, consumers, including Mr. Henderson, and prescribing physicians, that Defendants' Phenytoin product was safe when used as intended. Such misrepresentations, omissions, and concealments of facts include, but are not limited to:

a. Failing to disclose, and/or intentionally concealing, the results of tests showing the potential risks of serious skin reactions, erythema multiforme exudativum, bullous fixed drug eruption, severe cutaneous adverse reaction, acute generalized exanthematous pustulosis, drug reaction with eosinophilia and systemic symptoms, exfoliative dermatitis, toxic epidermal necrolysis, Stevens-Johnson Syndrome and other injuries associated with the use of Defendants' Phenytoin product;

b. Failing to include adequate warnings with Defendants' Phenytoin product about the potential and actual risks and the nature, scope, severity, and duration of serious adverse effects of Defendants' Phenytoin product;

c. Concealing and/or providing false or inaccurate information regarding the known risks of serious skin reactions, exfoliative dermatitis, toxic epidermal necrolysis, Stevens-Johnson Syndrome and other risks associated with Defendants' Phenytoin product; and

d. Concealing the known incidents of serious skin reactions, exfoliative dermatitis, toxic epidermal necrolysis, Stevens - Johnson syndrome and other injuries, as previously alleged herein.

95. Defendants intentionally concealed facts known to them, as alleged herein, in order to ensure increased sales of Defendants' Phenytoin product.

96. Defendants had a duty to disclose the foregoing risks and failed to do so, despite possession of information concerning those risks. Defendants' representations that Defendants' Phenytoin product was safe for its intended purpose were false, as Defendants' Phenytoin product was, in fact, dangerous to the health of Mr. Henderson, and caused his death. Moreover, Defendants knew that their statements were false, knew of incidents of serious injuries, such as serious skin reactions, erythema multiforme exudativum, bullous fixed drug eruption, severe cutaneous adverse reaction, acute generalized exanthematous pustulosis, drug reaction with eosinophilia and systemic symptoms, exfoliative dermatitis, toxic epidermal necrolysis, Stevens - Johnson syndrome, and knew that their omissions rendered their statements false or misleading.

97. Further, Defendants failed to exercise reasonable care in ascertaining the accuracy of the information regarding the safe use of Defendants' Phenytoin product, and failed to disclose that

Defendants' Phenytoin product caused serious skin reactions, erythema multiforme exudativum, bullous fixed drug eruption, severe cutaneous adverse reaction, acute generalized exanthematous pustulosis, drug reaction with eosinophilia and systemic symptoms, exfoliative dermatitis, toxic epidermal necrolysis, Stevens-Johnson Syndrome, among other serious adverse effects. Defendants also failed to exercise reasonable care in communicating the information concerning Defendants' Phenytoin product to Mr. Henderson, and/or concealed facts that were known to Defendant.

98. Mr. Henderson and his prescribing physician were not aware of the falsity of the foregoing representations, nor were Mr. Henderson and his prescribing physician aware that material facts concerning the safety of Defendants' Phenytoin product had been concealed or omitted. In reliance upon Defendants' misrepresentations (and the absence of disclosure of the serious health risks), Mr. Henderson ingested Defendants' Phenytoin product. Had Mr. Henderson and his prescribing physician known the true facts concerning the risks associated with Defendants' Phenytoin product, Mr. Henderson would not have taken it.

99. The reliance by Mr. Henderson and his prescribing physician upon Defendants' misrepresentations was justified because said misrepresentations and omissions were made by individuals and entities that were in a position to know the true facts concerning Defendants' Phenytoin product. Mr. Henderson and his prescribing physician were not in a position to know the true facts because Defendants aggressively promoted the use of Defendants' Phenytoin product and concealed the risks associated with their use, thereby inducing Mr. Henderson and his prescribing physician to use Defendants' Phenytoin product.

100. As a direct and proximate result of Defendants' misrepresentations, and/or concealment, Plaintiff suffered harm as alleged herein, including extreme pain and suffering, loss of enjoyment of life, ascertainable economic loss, including the purchase price of Defendants'

Phenytoin product, out-pocket costs of medical tests and treatment, future medical care and/or services, and other costs incidental to Mr. Henderson's ingestion of Defendants' Phenytoin product.

101. Defendants' conduct in concealing material facts and making the foregoing misrepresentations, as alleged herein, was committed with conscious or reckless disregard of the rights and safety of consumers such as Mr. Henderson, thereby entitling Plaintiff to punitive damages in an amount to be determined at trial that is appropriate to punish Defendants and deter them from similar conduct in the future.

COUNT IV
BREACH OF WARRANTIES

102. Plaintiff incorporates by reference each and every paragraph of this complaint as though set forth in full in this cause of action.

103. Defendants manufactured, marketed, sold, and distributed Defendants' Phenytoin product.

104. At the time Defendants marketed, sold, and distributed Defendants' Phenytoin product for use by Mr. Henderson, Defendants knew of the purpose for which Defendants' Phenytoin product was intended and impliedly warranted Defendants' Phenytoin product to be of merchantable quality and safe and fit for such use.

105. Mr. Henderson and his prescribing physicians reasonably relied on the skill, superior knowledge, and judgment of Defendants as to whether Defendants' Phenytoin product was of merchantable quality and safe and fit for its intended use.

106. Mr. Henderson used Defendants' Phenytoin product which was provided to Mr. Henderson's prescribing physician by the Defendant. Due to Defendants' wrongful conduct as alleged herein, Mr. Henderson could not have known about the risks and side effects associated with Defendants' Phenytoin product until after Mr. Henderson ingested it.

107. Contrary to such implied warranty, Defendants' Phenytoin product was not of merchantable quality and was not safe or fit for its intended use.

108. As a direct and proximate result of Defendants' breach of implied warranty, Plaintiff suffered harm as alleged herein, including extreme pain and suffering, loss of enjoyment of life, ascertainable economic loss, including the purchase price of Defendants' Phenytoin product, out-pocket costs of medical tests and treatment, future medical care and/or services, and other costs incidental to Mr. Henderson's ingestion of harmful and defective products.

109. Defendants' aforementioned conduct was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers such as Mr. Henderson, thereby entitling Plaintiff to punitive damages in an amount to be determined at trial that is appropriate to punish Defendants and deter them from similar conduct in the future.

COUNT V
NEGLIGENCE

110. Plaintiff incorporates by reference each and every paragraph of this complaint as though set forth in full in this cause of action.

111. Defendants owed a duty to consumers of Defendants' Phenytoin product, including Mr. Henderson, to use reasonable care in designing, testing, labeling, manufacturing, marketing, supplying, distribution and selling Defendants' Phenytoin product, including a duty to ensure that Defendants' Phenytoin product did not cause users to suffer from unreasonable, unknown, and/or dangerous side effects.

112. Defendants failed to exercise reasonable care in the warning about, designing, testing, labeling, manufacture, marketing, sale, and/or distribution of Defendants' Phenytoin product and breached their duties to Mr. Henderson in that, and not by way of limitation, they did not warn of the known risks associated with the use of Defendants' Phenytoin product and did not exercise an

acceptable standard of care, i.e., what a reasonably prudent manufacturer or seller would have known and warned about. Moreover, the product lacked sufficient warnings of the hazards and dangers to users of said product, and failed to provide safeguards to prevent the injuries sustained by Mr. Henderson. Defendants failed to properly test Defendants' Phenytoin product prior to its sale, and as a result subjected users to an unreasonable risk of injury when those products was used as directed and recommended.

113. Defendants additionally breached their duty and were negligent in their actions, misrepresentations, and omissions toward Mr. Henderson and his prescribing physician , in part, in the following ways:

a. Failed to exercise due care in designing, developing, and manufacturing Defendants' Phenytoin product so as to avoid the aforementioned risks to individuals using these products;

b. Failed to include adequate warnings with Defendants' Phenytoin product that would alert Mr. Henderson, his prescribing physician, and other consumers to its potential risks and serious side effects;

c. Failed to adequately and properly test Defendants' Phenytoin product before placing it on the market;

d. Failed to conduct sufficient testing on Defendants' Phenytoin product, which if properly performed, would have shown that Defendants' Phenytoin product had serious side effects, including, but not limited to, erythema multiforme exudativum, bullous fixed drug eruption, severe cutaneous adverse reaction, acute generalized exanthematous pustulosis, drug reaction with eosinophilia and systemic symptoms, exfoliative dermatitis, toxic epidermal necrolysis, Stevens-Johnson Syndrome and

other serious skin reactions;

e. Failed to adequately warn Mr. Henderson and physicians that use of Defendants' Phenytoin product carried a risk of serious skin reactions; erythema multiforme exudativum, bullous fixed drug eruption, severe cutaneous adverse reaction, acute generalized exanthematous pustulosis, drug reaction with eosinophilia and systemic symptoms, exfoliative dermatitis, toxic epidermal necrolysis, Stevens-Johnson Syndrome and other serious side effects;

f. Failed to provide adequate post-marketing warnings or instructions after Defendants knew, or should have known, of the significant risks of reactions from the use of Defendants' Phenytoin product;

g. Placed an unsafe product into the stream of commerce; and

h. Was otherwise careless or negligent.

114. Defendants knew, or should have known, that Defendants' Phenytoin product caused unreasonably dangerous risks and serious side effects of which Mr. Henderson and his prescribing physician would not be aware. Defendants nevertheless advertised, marketed, sold and/or distributed Defendants' Phenytoin product knowing of its unreasonable risks of injury.

115. Defendants knew or should have known that consumers such as Mr. Henderson would suffer injury as a result of Defendants' failure to exercise reasonable care as described above.

116. Upon information and belief, Defendants knew or should have known of the defective nature of Defendants' Phenytoin product, as set forth herein, but continued to design, manufacture, market, and sell Defendants' Phenytoin product so as to maximize sales and profits at the expense of the health and safety of the public, including Mr. Henderson, in conscious and/or negligent disregard of the foreseeable harm caused by Defendants' Phenytoin product.

117. Defendants failed to disclose to the Mr. Henderson, his prescribing physician, and the general public facts known or available to them, as alleged herein, in order to ensure continued and increased sales of Defendants' Phenytoin product. This failure to disclose deprived Mr. Henderson and his prescribing physician of the information necessary to weigh the true risks of taking Defendants' Phenytoin product against the benefits.

118. As a direct and proximate result of Mr. Henderson's use of Defendants' Phenytoin product, Mr. Henderson suffered serious bodily injury including, but not limited to, erythema multiforme exudativum, bullous fixed drug eruption, severe cutaneous adverse reaction, acute generalized exanthematous pustulosis, drug reaction with eosinophilia and systemic symptoms, Stevens-Johnson Syndrome, a severe adverse reaction, and skin a disorder.

119. By virtue of Defendants' negligence, Defendants directly, foreseeably and proximately caused Mr. Henderson to suffer serious bodily injury. As a result, the imposition of punitive damages against Defendants is warranted.

120. As a direct and proximate result of Defendants' negligence, Plaintiff suffered harm as alleged herein, including severe pain and suffering, loss of enjoyment of life, ascertainable economic loss, including the purchase price of Defendants' Phenytoin product, out-pocket costs of medical tests and treatment, future medical care and/or services, and other costs incidental to Mr. Henderson's ingestion of harmful and defective products.

COUNT VI
GROSS NEGLIGENCE

121. Plaintiff incorporates by reference each and every paragraph of this complaint as though set forth in full in this cause of action.

122. Defendants had a duty to exercise reasonable care in the warning about, design, testing, manufacture, marketing, labeling, sale, and/or distribution of Defendants' Phenytoin

product, including a duty to ensure that Defendants' Phenytoin product did not cause users to suffer from unreasonable and dangerous side effects.

123. Defendants failed to exercise reasonable care in the warning about, design, testing, manufacture, marketing, labeling, sale, and/or distribution of Defendants' Phenytoin product, in that Defendants knew or should have known that taking Defendants' Phenytoin product caused unreasonable and life-threatening injuries, as alleged herein.

124. Defendants was grossly negligent in the warning about, design, testing, manufacture, marketing, labeling, sale, and/or distribution of Defendants' Phenytoin product in that they:

a. failed to provide adequate warnings with Defendants' Phenytoin product regarding their possible risks and adverse effects as well as the comparative severity and duration of such adverse effects;
b. failed to exercise due care in designing, developing, and manufacturing Defendants' Phenytoin product so as to avoid the aforementioned risks to individuals;
c. placed unsafe product into the stream of commerce; and
d. was otherwise grossly negligent.

125. Although Defendants knew, or recklessly disregarded, the fact that Defendants' Phenytoin product caused potentially lethal side effects, Defendants continued to market Defendants' Phenytoin product to consumers, including Mr. Henderson, without disclosing these side effects.

126. Defendants knew and/or consciously or recklessly disregarded the fact that consumers such as Mr. Henderson would suffer injury as a result of Defendants' failure to exercise reasonable care as described above.

127. Defendants knew of, or recklessly disregarded the defective nature of Defendants' Phenytoin product, as set forth herein, but continued to design, manufacture, market, and sell Defendants' Phenytoin product so as to maximize sales and profits at the expense of the health and safety of the public, including Mr. Henderson, in conscious and/or reckless disregard of the foreseeable harm caused by Defendants' Phenytoin product.

128. As a direct and proximate result of the gross negligence, willful and wanton misconduct, or other wrongdoing and actions of Defendants described herein, which constitute a deliberate act or omission with knowledge of a high degree probability of harm and reckless indifference to the consequences, Plaintiff suffered harm as previously alleged herein, including ascertainable economic loss, including the purchase price of Defendants' Phenytoin product, out-of-pocket costs of medical tests and treatment, future medical care and/or services, and other costs incidental to Mr. Henderson's ingestion of Defendants' harmful and defective Phenytoin product. In addition, Mr. Plaintiff was rendered sick, blistered and scarred, both internally and externally, and died as a result. All of said injuries have caused and continue to cause Plaintiff intense anxiety, distress, fear, pain, suffering, and distress secondary to the physical injury and damages. In addition, Plaintiff have suffered other injuries; the exact nature and extent are not known at this time.

129. Defendants' aforementioned conduct was committed with knowing, conscious, and/or deliberate disregard for the rights and safety of consumers such as Mr. Henderson, thereby entitling Plaintiff to punitive damages in an amount appropriate to punish Defendants and deter them from similar conduct in the future. Defendants continued to promote the efficacy and safety of Defendants' Phenytoin product, while providing little or no warnings, and downplayed any risks, even after Defendants knew of the risks and injuries associated with their use.

COUNT VII
JOINT AND SEVERAL LIABILITY

130. Plaintiff incorporates by reference all of the paragraphs of this Complaint as if fully set forth herein.

131. By virtue of their individual and collective acts and omissions, Defendants are jointly and severally liable to Plaintiff as such acts and omissions have proximately caused Plaintiff to suffer a single indivisible injury for which each Defendant is responsible.

COUNT VIII
PUNITIVE DAMAGES

132. Plaintiff incorporates by reference all of the paragraphs of this Complaint as if fully set forth herein.

133. Defendants' conduct set forth herein was intentional, willful wanton, oppressive, malicious, and reckless, evidencing such an entire want of care as to raise the presumption of a conscious indifference to the consequences in that Defendants acted only out of self interest and personal gain. Such conduct evidences a specific intent to cause harm to Plaintiffs as provided under O.C.G.A. § 51-12-5.1. Accordingly, punitive damages should be imposed against Defendants pursuant O.C.G.A. § 51-12-5.1 and others applicable laws, to punish and deter Defendants from repeating or continuing such unlawful conduct.

WHEREFORE, Plaintiff prays:

(a) That process issue according to law;

(b) That each Defendant be served with a copy of Plaintiffs' Complaint For Damages and show cause why the prayers for relief requested by Plaintiffs herein should not be granted;

(c) That Plaintiffs be granted a **trial by jury** in this matter;

(d) That the Court enter a judgment against each Defendant, jointly and severally, for all general and compensatory damages allowable to Plaintiffs;

(e) That the Court enter a judgment against each Defendant, jointly and severally, for all special damages allowable to Plaintiffs;

(f) That the Court enter a judgment against each Defendant serving to award Plaintiffs punitive damages under the provisions of O.C.G.A. § 51-12-5.1;

(g) That the Court enter a judgment against each Defendant, jointly and severally, for all other relief sought by Plaintiff under this Complaint;

(h) That the costs of this action be cast upon Defendants; and

(i) That the Court grant Plaintiff such further relief which the Court deems just and appropriate.

Respectfully submitted this 8th day of March, 2011.

/s/ C. Andrew Childers
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